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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,285	02/18/2004	Justin Stephen Bryans	PC25539A	4206

28523 7590 11/23/2005  
PFIZER INC.  
PATENT DEPARTMENT, MS8260-1611  
EASTERN POINT ROAD  
GROTON, CT 06340

EXAMINER
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GRAZIER, NYEEMAH

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 11/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/782,285

Applicant(s)

BRYANS ET AL.

Examiner

Nyeemah Grazier

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 17, 18 and 20-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 19 is/are rejected.
- 7) ☒ Claim(s) 2-16 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                                    |

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**DETAIL ACTION**  
First Action on the Merits

I. ACTION SUMMARY

Claims 1-26 are currently pending. Claims 17, 18 and 20-26 are withdrawn from further consideration by the Examiner because they are drawn to a non-elected invention. 37 C.F.R. § 1.142(b).

II. PRIORITY

This application repeats a substantial portion of prior Application No. 60/455,455, filed March 18, 2003, and adds and claims additional disclosure not presented in the prior application. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 FR 1.78.

III. RESPONSE TO ELECTION/RESTRICTION

Applicant's election of Group I, claims 1-16 and 19 and election of Example 5 as a provisional specie election in the response filed on October 5, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant request that Examiner re-join the method of treatment claims (17 and 18) and all process of manufacture claims (claims 21-26). (See Remarks, p. 2-3). Upon the determination that the elected Group (claims 1-16 and 19) are allowable the method claims and a process of

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making the product claim will be rejoined as mentioned in the Restriction Letter. (See Action, Section: Advisory of Rejoinder, pp. 9-12) However, the instant application is drawn to more than one process of manufacture. Where there is more than one process of making is claimed along with the product claims, the first recited process is considered to form part of the main invention. See 37 CFR 1.475(d).

#### STATUS OF THE CLAIMS

Applicant elected Example 5, 8-chloro-5-methyl-1-(3, 4, 5, 6-tetrahydro-2H-[1,2']bipyridinyl-4-yl)-5,6-dihydro-4H-2,3,5,10b tetraaza-benzo[e]azulene disclosed on page 95 of the Specification. This election of specie was for search purposes. Therefore, Formula (I) was examined wherein:

V is (CH<sub>2</sub>)<sub>d</sub>(O)<sub>e</sub> and d is 1 and e is 0;

W is N(R<sub>1</sub>) and R<sub>1</sub> is as defined in claim 1;

X and Y are defined in claim 1;

Z is (CH<sub>2</sub>)<sub>f</sub>(O)<sub>g</sub> and f is 1 and g is 0;

Ring A and Ring B are defined in claim 1.

#### EXTENDED PRIOR ART SEARCH PURSUANT TO MPEP 803.02

If upon examination of the elected species, no prior art is found that would anticipate or render obvious the instant invention based on the elected species, the search of the Markush-type claim will be extended. See M.P.E.P. § 803.02 (2001). If prior art is then found that anticipates or renders obvious the non-elected species, the Markush-type claim will be rejected. It should be noted that the prior art search will not be extended unnecessarily to cover all non-elected species.

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Should Applicant overcome the rejection by amending the claim, the amended claim will be reexamined. Id. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. Id. In the event prior art is found during reexamination that renders obvious or anticipates the amended Markush-type claim, the claim will be rejected and the action made final. Id.

As indicated above, Examiner searched the compound based on the elected species, Example 5 in response to the requirement to restrict the products of Formula (I), wherein: However, there was no prior art of record that anticipated or rendered obvious the elected species and therefore the scope of the subject matter was **extended or broaden** in pursuant to M.P.E.P. § 803.02. The prior art search was extended to include all of the Formula (I) and its variables as defined in claim 1.

#### IV. REJECTIONS

##### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the compound of formula (I) or “a pharmaceutically acceptable derivative thereof.” (See p. 151, line 6). The Specification provides the following disclosure for “derivatives.” (Spec, p. 7, ll. 29-35).

Pharmaceutically acceptable derivatives of the compounds of formula (I) according to the invention include salts, solvates, complexes, polymorphs, prodrugs, stereoisomers, geometric isomers, tautomeric forms, and isotopic variations of compounds of formula (I). Preferably, pharmaceutically acceptable derivatives of compounds of formula (I) comprise salts, solvates, esters and amides of the compounds of formula (I). More preferably,

The term “derivative” is indefinite because it is unclear what the invention or what type of derivative you envision as the invention. The Specification provides some guidance, but the definition for some of the derivatives are “open ended.” The abovementioned objection under 35 U.S.C. §112, 2<sup>nd</sup> will be obviated by the following suggestions:

Delete the term “derivative” and insert pharmaceutical acceptable salts and stereoisomers.

***Provisional Obviousness-Type Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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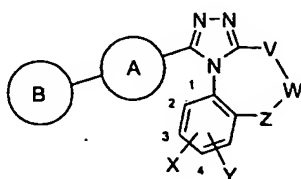
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 19 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/865,194 (US 2005/0049255 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasoning.

The analysis employed in an obviousness-type double patent rejection is consistent with a §103(a) analysis set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966).

Although the conflicting claims are not identical, they are not patentably distinct from each other because: Instant claim 19 recites "a pharmaceutical formulation comprising a compound according to Claim 1 together with pharmaceutically acceptable excipient, diluent or carrier. Claim 1 is drawn to the compound of formula (I) or a pharmaceutically acceptable derivative thereof.

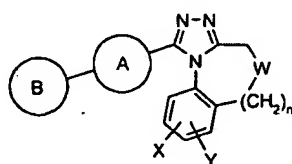


(II)

The compounds of formula (I) are vasopressin receptor V1a antagonist for the treatment of dysmenorrhea.

### Scope and Contents of the Co-pending Application

Conflicting Claim 1 of the co-pending application, US 2005/0049255 recites a pharmaceutical composition comprising a PDE inhibitor or a pharmaceutically acceptable derivative thereof, and a vasopressin receptor family antagonist, or a pharmaceutically acceptable derivative thereof. (p. 20, line 262). The composition is also used for the treatment of dysmenorrhea. Formula (I) is an example of "V1a antagonist used with the invention." (p. 7, ll. 72-85). Formula (I) is the following:



(I)

Formula (I) is a subgenus of Instant Formula (I) as the variable meaning overlap with the instant invention.

### Ascertaining the Differences Between the Copending Application and the Instant Claims

The difference between the instant claims and the copending application is in scope. Both application claim compositions with open-ended transitional phrases. The instant invention



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recites a pharmaceutical composition of formula (I) "comprising" an excipient, diluent or carrier. In the copending application, the claim also recites a pharmaceutical composition of formula (I) which is instant formula (I) wherein V is CH<sub>2</sub> and Z is (CH<sub>2</sub>)<sub>1-2</sub> but also a PDE inhibitor, or a pharmaceutical acceptable derivative thereof. Since, instant claim 19 contains open-ended language, instant claim 19 could comprise a PDE inhibitor.

*Resolving the Level of Ordinary Skill in the Pertinent Art*

It would have been obvious to one of ordinary skill to make or use the compounds of the instant invention. Also, because the structure similarity of the compound of invention in the copending application and the compound because similar compounds are generally expected to have similar properties and have similar utilities. In re Gyurik, 596 F.2d 1012, 201 USPQ 552 (CCPA 1979).

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application that matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

V. **OBJECTIONS**

*Claim Objections*

Claim 16 is objected to because of the following informalities: Claim 16 recites “tricycle[9.4.0.0\*2,6\*]” on lines 8 and 10 on page 154 of the Specification. Appropriate correction is required.

*Allowable Subject Matter*

Claims 2-16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**CONCLUSION**

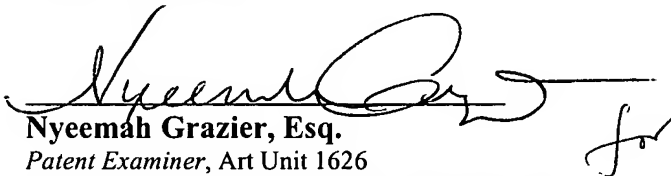
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nyeemah Grazier whose telephone number is (571) 272-8781. The examiner can normally be reached on Monday through Thursday and every other Friday from 8:30 a.m. - 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (571) 272 - 0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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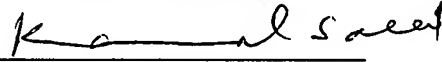
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Very truly yours,



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